Drug Enforcement Administration

[Docket No. DEA-1176]

Bulk Manufacturer of Controlled Substances Application: SpecGx LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: SpecGx LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Such persons may also file a written request for a hearing on the application on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to https://www.regulations.gov and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on https://www.regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on February 14, 2023, SpecGx LLC, 3600 North 2nd Street, Saint Louis, Missouri 63147-

3457, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821 I Butyryl Fentanyl 9822 I Fentanyl related-compounds as defined in 21 CFR 1308.11(h) 9850 I Amphetamine 1100 II Methamphetamine 1105 II Lisdexamfetamine 1205 II Methylphenidate 1724 II Nabilone 7379 II ANPP (4-Anilino-N-phenethyl-4-piperidine) 8333 II Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II	Controlled Substance	Drug Code	Schedule
Psilocybin 7437 I Codeine-N-oxide 9053 I Noroxymorphone 9145 I Difenoxin 9168 I Morphine-N-oxide 9307 I Normorphine 9313 I Alphamethadol 9605 I Betamethadol 9609 I Norlevorphanol 9634 I Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821 I Butyryl Fentanyl 9822 I Fentanyl related-compounds as defined in 21 CFR 1308.11(h) 9850 I Amphetamine 1100 II Methamphetamine 1105 II Lisdexamfetamine 1205 II Methylphenidate 1724 II Nabilone 7379 II ANPP (4-Anilino-N-phenethyl-4-piperidine) 8333 II Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II	Gamma Hydroxybutyric Acid	2010	I
Codeine-N-oxide 9053 I Noroxymorphone 9145 I Difenoxin 9168 I Morphine-N-oxide 9307 I Normorphine 9313 I Alphamethadol 9605 I Betamethadol 9609 I Norlevorphanol 9634 I Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821 I Butryrl Fentanyl 9822 I Fentanyl related-compounds as defined in 21 CFR 1308.11(h) 9850 I Amphetamine 1100 II Methylphenidate 1105 II Methylphenidate 1724 II Nabilone 7379 II ANPP (4-Anilino-N-phenethyl-4-piperidine) 8333 II Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II <tr< td=""><td>Tetrahydrocannabinols</td><td>7370</td><td>I</td></tr<>	Tetrahydrocannabinols	7370	I
Noroxymorphone	Psilocybin	7437	I
Difenoxin 9168 I Morphine-N-oxide 9307 I Normorphine 9313 I Alphamethadol 9605 I Betamethadol 9609 I Norlevorphanol 9634 I Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821 I Butyryl Fentanyl 9822 I Fentanyl related-compounds as defined in 21 CFR 1308.11(h) 9850 I Amphetamine 1100 II Methylphenidate 1105 II Methylphenidate 1724 II Nabilone 7379 II ANPP (4-Anilino-N-phenethyl-4-piperidine) 8333 II Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Eegonine 9180 II	Codeine-N-oxide	9053	I
Morphine-N-oxide 9307 1 Normorphine 9313 1 Alphamethadol 9605 1 Betamethadol 9609 1 Norlevorphanol 9634 1 Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821 1 Butyryl Fentanyl 9822 1 Fentanyl related-compounds as defined in 21 CFR 1308.11(h) 9850 1 Amphetamine 1100 II Methamphetamine 1105 II Lisdexamfetamine 1205 II Methylphenidate 1724 II Nabilone 7379 II ANPP (4-Anilino-N-phenethyl-4-piperidine) 8333 II Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II <	Noroxymorphone	9145	I
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Alphamethadol 9605 I	Morphine-N-oxide	9307	I
Betamethadol 9609	Normorphine	9313	I
Norlevorphanol 9634	Alphamethadol	9605	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) 9821 I	Betamethadol	9609	I
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Amphetamine 1100 II Methamphetamine 1105 II Lisdexamfetamine 1205 II Methylphenidate 1724 II Nabilone 7379 II ANPP (4-Anilino-N-phenethyl-4-piperidine) 8333 II Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Methadone 9250 II Methadone intermediate 9254 II Dextropropoxyphene, bulk (non-dosage forms)	Butyryl Fentanyl	9822	I
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Phenylacetone 8501 II Codeine 9050 II Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Methadone 9250 II Methadone intermediate 9250 II Dextropropoxyphene, bulk (non-dosage forms) 9273 II Morphine 9300 II	Nabilone	7379	II
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Dihydrocodeine 9120 II Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Meperidine intermediate-C 9234 II Methadone 9250 II Methadone intermediate 9254 II Dextropropoxyphene, bulk (non-dosage forms) 9273 II Morphine 9300 II	Phenylacetone	8501	II
Oxycodone 9143 II Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Meperidine intermediate-C 9234 II Methadone 9250 II Methadone intermediate 9254 II Dextropropoxyphene, bulk (non-dosage forms) 9273 II Morphine 9300 II	Codeine	9050	II
Hydromorphone 9150 II Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Meperidine intermediate-C 9234 II Methadone 9250 II Methadone 9250 II Methadone 9251 II	Dihydrocodeine	9120	II
Diphenoxylate 9170 II Ecgonine 9180 II Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Meperidine intermediate-C 9234 II Methadone 9250 II Methadone 9250 II Methadone 9254 II Dextropropoxyphene, bulk (non-dosage forms) 9273 II Morphine 9300 II	Oxycodone	9143	II
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Hydrocodone 9193 II Levorphanol 9220 II Isomethadone 9226 II Meperidine 9230 II Meperidine intermediate-A 9232 II Meperidine intermediate-B 9233 II Meperidine intermediate-C 9234 II Methadone 9250 II Methadone 9250 II Methadone intermediate 9254 II Dextropropoxyphene, bulk (non-dosage forms) 9273 II Morphine 9300 II	Diphenoxylate	9170	II
Levorphanol9220IIIsomethadone9226IIMeperidine9230IIMeperidine intermediate-A9232IIMeperidine intermediate-B9233IIMeperidine intermediate-C9234IIMethadone9250IIMethadone intermediate9254IIDextropropoxyphene, bulk (non-dosage forms)9273IIMorphine9300II	Ecgonine	9180	II
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Meperidine intermediate-C9234IIMethadone9250IIMethadone intermediate9254IIDextropropoxyphene, bulk (non-dosage forms)9273IIMorphine9300II	Meperidine intermediate-A	9232	II
Methadone9250IIMethadone intermediate9254IIDextropropoxyphene, bulk (non-dosage forms)9273IIMorphine9300II	Meperidine intermediate-B	9233	II
Methadone intermediate9254IIDextropropoxyphene, bulk (non-dosage forms)9273IIMorphine9300II	Meperidine intermediate-C	9234	II
Dextropropoxyphene, bulk (non-dosage forms) 9273 II Morphine 9300 II	Methadone	9250	II
Morphine 9300 II	Methadone intermediate	9254	II
Morphine 9300 II	Dextropropoxyphene, bulk (non-dosage forms)	9273	II
		9300	II
		9330	II

Thebaine	9333	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Tapentadol	9780	II
Fentanyl	9801	II
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Pentobarbital	2270	II
4-Anilino-N-Phenethyl-4-Piperidine (ANPP)	8333	II
Tapentadol	9780	II
Fentanyl	9801	II

The company plans to bulk manufacture the listed controlled substances for sale to its customers as Active Pharmaceutical Ingredients (APIs) and Analytical Research Standards (ARS) for formulation and analytical development purposes. In reference to dug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Matthew Strait,

Deputy Assistant Administrator.

[FR Doc. 2023-06952 Filed: 4/3/2023 8:45 am; Publication Date: 4/4/2023]